

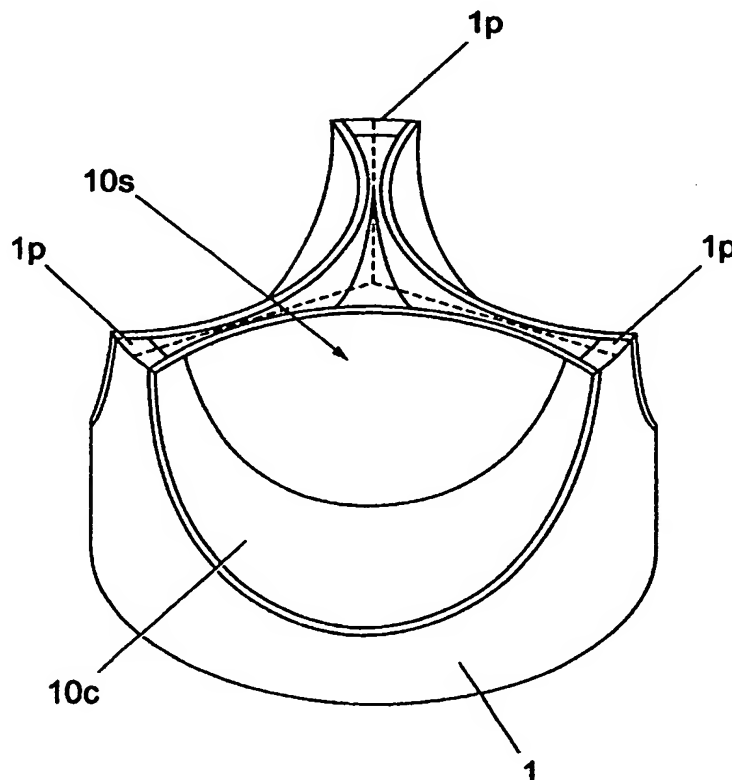


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(21) International Application Number: PCT/GB98/00211 (22) International Filing Date: 22 January 1998 (22.01.98) (30) Priority Data: 9701479.9 24 January 1997 (24.01.97) GB (71) Applicant (for all designated States except US): AORTECH EUROPE LIMITED [GB/GB]; Strathclyde Business Park, Bellshill ML4 3NJ (GB). (72) Inventors; and (75) Inventors/Applicants (for US only): WHEATLEY, David, John [GB/GB]; 13 Lochend Drive, Glasgow G61 1ED (GB). FISHER, John [GB/GB]; 12 Birch Mews, Adel, Leeds LS16 8NY (GB). WILLIAMS, David [GB/GB]; Haydan Cottage, Castle Hill, Kingsley, Frodsham, Cheshire WA6 6JS (GB). (74) Agent: MURGITROYD & COMPANY; 373 Scotland Street, Glasgow G5 8QA (GB).		(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>

(54) Title: HEART VALVE PROSTHESIS**(57) Abstract**

The invention provides a prosthetic valve having a generally annular frame with three post and three scallops. The frame is tri-symmetric with an axis of symmetry defined by the axis of blood flow through the valve. The external surface of the frame is generally cylindrical with diameter D. Each leaflet has a truncated spherical surface adjacent to its free edge. The spherical surface is joined tangentially to a truncated conical surface. The half angle of the truncated cone is approximately 37.5°. The radius of the sphere is approximately $D/2 - 0.5$ (mm). The leaflet surface is axi-symmetrical with the axis of symmetry being perpendicular to the axis of the valve frame and blood flow.



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1 HEART VALVE PROSTHESIS

2

3 The present invention relates to medical implants,
4 particularly cardiac and vascular implants and
5 prostheses.

6

7 In mammals the heart is a vital organ responsible for
8 maintaining an adequate flow of blood (and hence oxygen
9 and nutrients) to all parts of the body. The blood is
10 prevented from flowing backwards through the heart by
11 valves.

12

13 Dysfunction of one or more of the valves in the heart
14 can have serious medical consequences. Dysfunction of
15 heart valves may be the result of a congenital defect,
16 or of disease-induced damage or degeneration.
17 Dysfunction results from stenosis or regurgitation (or a
18 combination) of the valve, leading to high pressure
19 upstream of the valve.

20

21 To date, the only solution to treat some heart valve
22 dysfunctions is to replace the malfunctioning valve.
23 Such a valve replacement operation is expensive and
24 requires specialised facilities for open-heart surgery.
25 Replacement of failed artificial valves carries

1 increased risk and there are practical limits on the
2 number of times that reoperation can be undertaken.
3 This makes the design and operational lifetime of any
4 replacement valve extremely important.

5
6 Porcine aortic valves have been used for many years in
7 human patients and it has been proposed (see for
8 example EP-A-0,402,036 of Pro Medica International Inc)
9 to use porcine pulmonary valves in human patients;
10 however, valves derived from biological material have a
11 finite lifetime and must generally be replaced within
12 10 years of implantation in younger patients.

13
14 In third world countries where rheumatic fever is still
15 common, the problems of valve replacement in young
16 patients are considerable. Anticoagulants (required
17 for mechanical valves) are often impractical;
18 accelerated calcification (a problem of biological
19 valves in the young) precludes the use of biological
20 alternatives.

21
22 In the Western world, increasing life expectancy for
23 humans results in a corresponding rise in patients
24 requiring cardiac valve replacement. There is thus an
25 increasing need for cardiac valve prostheses having
26 both an extended useful lifetime and also a low risk of
27 inducing thrombosis in a recipient.

28
29 Conventional flexible leaflet heart valves are known to
30 comprise an annular frame disposed parallel to the
31 blood flow. The annular frame generally has three posts
32 extending in the downstream direction defining three
33 generally U-shaped openings or scallops between the
34 posts. The leaflets are generally attached to the
35 frame between the posts along the edges of the scallops
36 and are unattached at the free edges of the leaflets

1 adjacent to the downstream ends of the posts.

2

3 According to the present invention there is provided a
4 cardiac valve prosthesis comprising a frame and two or
5 more leaflets attached to the frame, wherein at least
6 one of the leaflets comprises a first portion which has
7 a generally spherical surface, and/or a second portion
8 which has a generally conical surface.

9

10 The respective surfaces are preferably partially
11 conical or spherical.

12

13 The prosthesis may be an artificial valve and may be
14 oriented in a particular direction in a heart (or other
15 vascular tissue) to allow flow of blood in one
16 direction through the tissue but prevent back-flow.
17 The frame preferably has a generally circular cross
18 section with two or more posts (in an equal number to
19 the number of leaflets) extending in the same direction
20 from a base. The prosthesis is preferably oriented with
21 the posts of the frame extending in the downstream
22 direction such that the mouth of the valve formed by
23 the base is held open. The leaflets are attached to
24 the frame between the posts and each has a free edge
25 adjacent to the ends of the posts which can seal
26 together to close the valve at the ends of the posts.

27

28 The conical portion is preferably located adjacent to
29 the base of the prosthesis, and the spherical portion
30 is preferably located adjacent to the free edge. This
31 is advantageous in that the spherical surfaces at the
32 leaflet edges seal more effectively than planar or
33 conical surfaces, and the conical portion at the base
34 of the valve opens more readily upon the increase of
35 blood pressure in that vicinity than an equivalent
36 spherical portion.

1 A valve embodying the invention has low opening
2 resistance owing to the conical portion reacting first
3 to the increased pressure on the upstream side of the
4 valve. When closed, the increased pressure on the
5 downstream side of the valve forces the free edges of
6 the leaflets together in a substantially parallel
7 arrangement thereby enhancing the seal between the
8 leaflets and reducing the backflow of blood through the
9 valve.

10

11 The spherical portion adjacent to the base of the
12 leaflets also confers advantages in the stress
13 distribution when the valve is closed and the pressure
14 is greater downstream than upstream.

15

16 The leaflets may (but need not) be identical.

17

18 The leaflets preferably number three and the frame
19 comprises three posts.

20

21 The leaflets are preferably flexible.

22

23 The leaflets may have a defined boundary between the
24 first (spherical) portion and the second (conical)
25 portion, or alternatively, the boundary between these
26 two portions may be phased, for example by adopting a
27 sphere of gradually increasing radius merging with the
28 conical portion. This is acceptable provided that the
29 free edge of the leaflets (or a portion thereof) has a
30 generally spherical surface.

31

32 In one embodiment the leaflets extend beyond the top of
33 the posts of the frame.

34

35 The leaflets can comprise any biostable, biocompatible
36 thermoplastic elastomer including but not limited to

1 any polyurethane or silicone elastomer or any copolymer
2 or blend based on these elements.

3

4 The fabrication route can be any appropriate method,
5 including not only dip moulding but also injection
6 moulding, transfer moulding and similar procedures.

7

8 Preferably the leaflets comprise a biostable
9 polyurethane, such as ELASTEON-CSIRO, CHRONOFLEX or
10 TECOTHANE and are dip moulded thereby integrating the
11 leaflets to the supporting frame and posts.

12

13 The leaflets may be approximately 100-200 μm , but the
14 thickness can vary with the material used. The
15 leaflets can themselves vary in thickness, so as to
16 incorporate thick-walled areas and adjacent thin-walled
17 areas. Ridges and/or smooth progressions from thick to
18 thin walled areas are envisaged.

19

20 The leaflet surface is preferably axi-symmetrical, with
21 the axis of symmetry being perpendicular to the axis of
22 the valve frame and the intended direction of blood
23 flow. Where the diameter of the frame is distance
24 $D(\text{mm})$, the radius of the sphere preferably lies between
25 $D/2(\text{mm})$ and $(D/2)-2(\text{mm})$.

26

27 The conical portion is generally truncated and has a
28 half angle within the range 30° to 45° (eg preferably
29 37.5°).

30

31 The frame can be parallel or slightly tapered on the
32 inside and outside, so as to allow a slightly diverged
33 flow.

34

35 The pressure required to open the valve is defined by
36 the equation $\frac{Et^3}{R}$ where E is the elastic modulus, t is

37

R

1 the leaflet thickness and R is the radius of curvature.

2

3 Reversal of the curvature in the centre of the
4 leaflet(s) may also facilitate an opening of the valve.

5

6 The prothesis may have incorporate an escape path for
7 trapped air, eg a bleed hole in the frame and/or in one
8 or more leaflets, optionally near the base of each
9 leaflet leading through the frame to the inflow aspect
10 for de-airing of the sub-leaflet space.

11

12 Means for protecting the valve from post ensnarement
13 with an implanting suture is useful. This could take
14 the form of a simple extractable suture linking the
15 tips of the posts, or a more sophisticated umbrella-
16 like flexible polyurethane shield (not shown) which
17 could be collapsed and withdrawn through the mitral
18 prosthesis.

19

20 A metal frame may be used and the frame can be dip
21 coated with polymer and with facilities for enhancing
22 metal-polymer adhesion. The metal may be titanium or
23 titanium-alloy although any implantable metallic
24 material may be appropriate such as stainless steel or
25 cobalt-chromium alloys.

26

27 Alternatively a polymer material may be used for the
28 frame. Two preferred options are a rigid polyurethane
29 and PEEK, polyetheretherketone. Alternative polymers
30 are Delrin (a polyacetal), polyethylene and
31 polysulphone. Any rigid or semi-rigid thermoplastic
32 polymer such as a polyurethane, PEEK, polyacetal,
33 polyethylene, polysulphone, acrylic or similar
34 materials may be used.

35

36 Surface modifications to improve biocompatibility may

1 include any of these useful in relation to medical
2 device technology in general.

3
4 Surface modifications may be to control the
5 interactions between the valve material and blood in
6 order to prevent protein adsorption, platelet
7 attachment and activation, activation of the clotting
8 cascade and calcification. It is preferable to coat
9 any surface of the valve, primarily including but not
10 limited to the leaflet material.

11
12 The surface modification most likely to result in
13 reduced protein adsorption is that of the attachment of
14 phospholipids to the polymer. The principle is that a
15 phospholipid, such as phosphorylcholine, is attached to
16 the polymer surface, this layer mimicking the surface
17 of cells and being resistant to the adsorption of
18 plasma proteins. Since this adsorption is the first
19 event in blood-polymer interactions that triggers all
20 reactions with the clotting cascade and platelets, the
21 inhibition of the process delays or prevents these
22 other effects. Known technologies can be used to coat
23 any type of synthetic prosthetic heart valve. The
24 polymer used for the construction of the valve may be
25 coated with any biomimetic substance, such as a
26 protein, glycoprotein or phospholipid analogue, for the
27 purpose of minimising plasma protein adsorption onto
28 its surface.

29
30 A further possibility involves the attachment of
31 antibodies to a surface in order to control the nature
32 of a protein that is adsorbed. For example, it is
33 known that surfaces covered with a layers of albumin
34 are far less thrombogenic than surfaces covered with
35 fibrinogen. Attempts have been made to coat polymers
36 with these proteins but there are many immunological

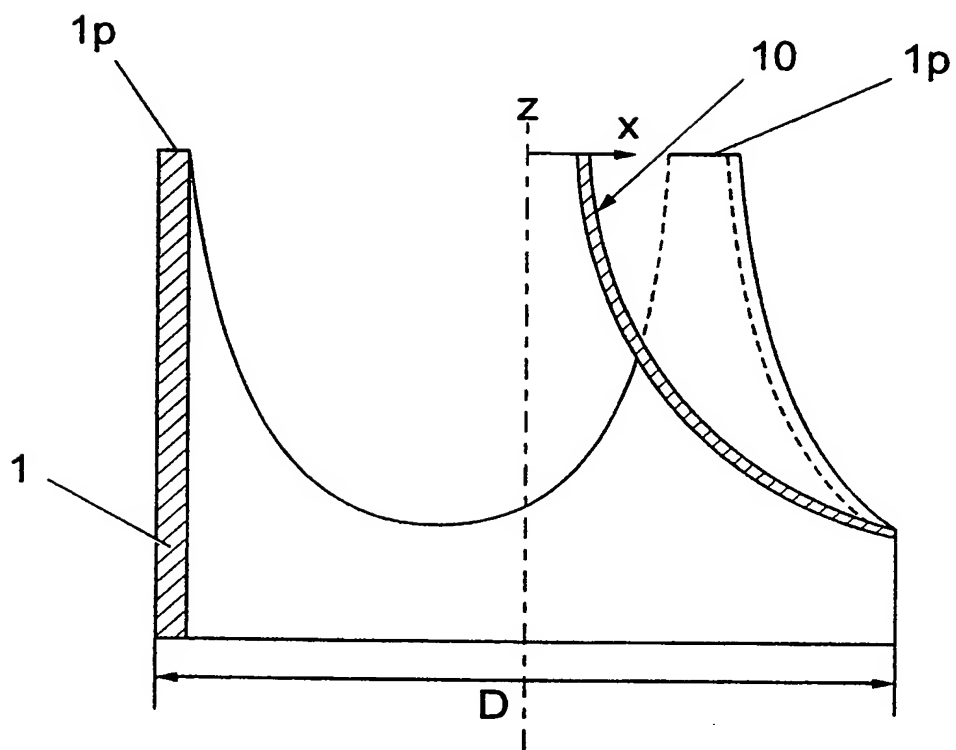
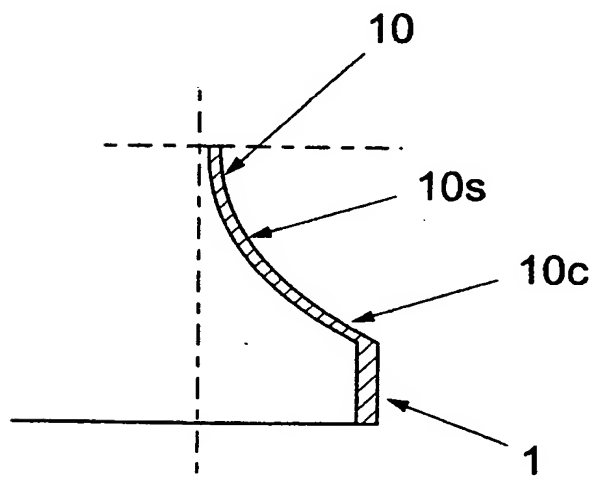
1 problems associated with the use of proteins derived
2 from sources other than the host. The better concept
3 is to employ anti-albumin antibodies which can be
4 attached to the surface such that when the material
5 comes into contact with the patient's blood, their own
6 albumin becomes strongly attached to the bound
7 antibody.

8
9 Platelets have a tendency to interact with all foreign
10 surfaces but this process can be minimised by control
11 of the surface composition and characteristics. It is
12 important to prevent platelets from attaching to the
13 surface but also to prevent any attached platelets from
14 being activated at or near that surface. A surface
15 modification process that could be beneficial involves
16 the attachment of hydrophilic molecules onto the
17 polymer surface. Polyethylene glycol or other similar
18 substances may be covalently attached to polymers such
19 as polyurethane and the imparted hydrophilicity will
20 reduce the tendency for cellular attachment.

21
22 Platelet attachment may also be resisted by the use of
23 pharmacologically active agents attached to the
24 surface. Drugs such as prostaglandin, heparin,
25 hirudin, t-plasminogen activator and urokinase have
26 been attached to functionalised polymer surfaces or
27 otherwise incorporated as leachable or diffusable
28 components of polymers for this purpose. These
29 molecules are known to have anti-platelet activity
30 through their effect on platelet membranes and/or their
31 effect on components of the clotting cascade which
32 interact with these membranes and it is possible to
33 reduce platelet attachment and activation.

34
35 One or more parts of the prosthesis can be transparent.
36

4 / 8

*Fig. 4a**Fig. 4b*

5 / 8

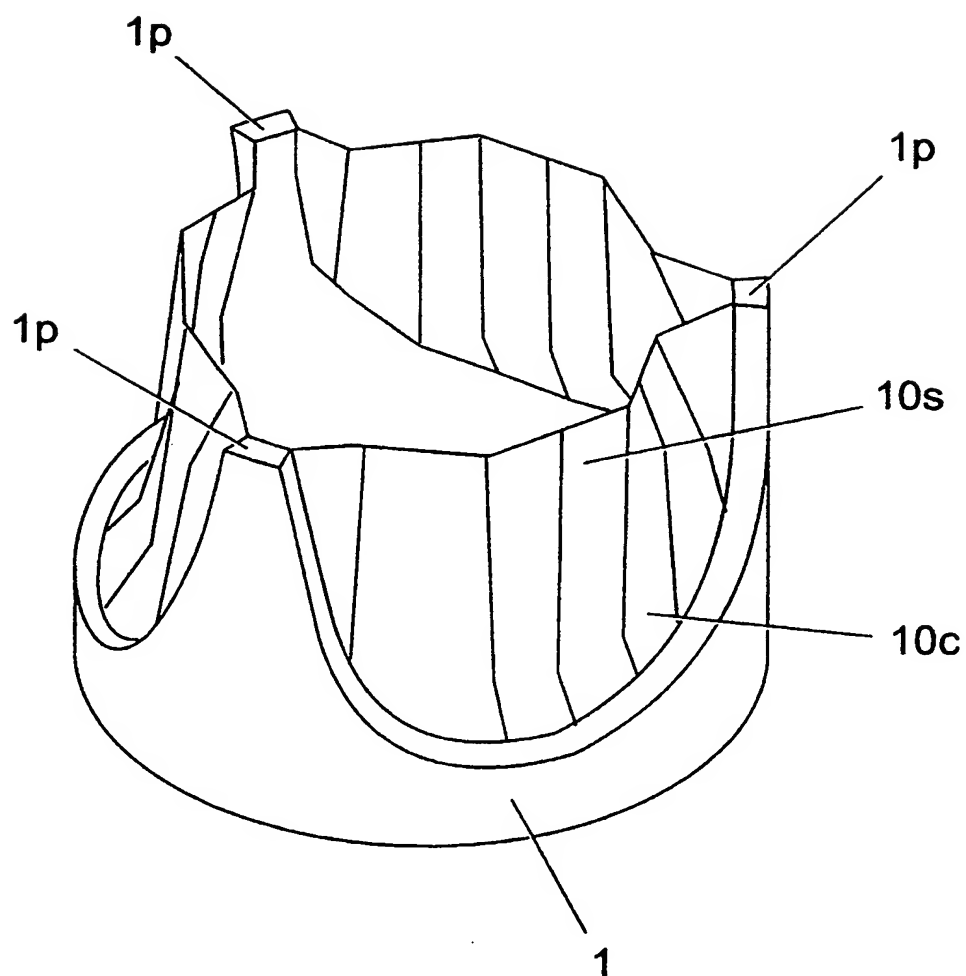
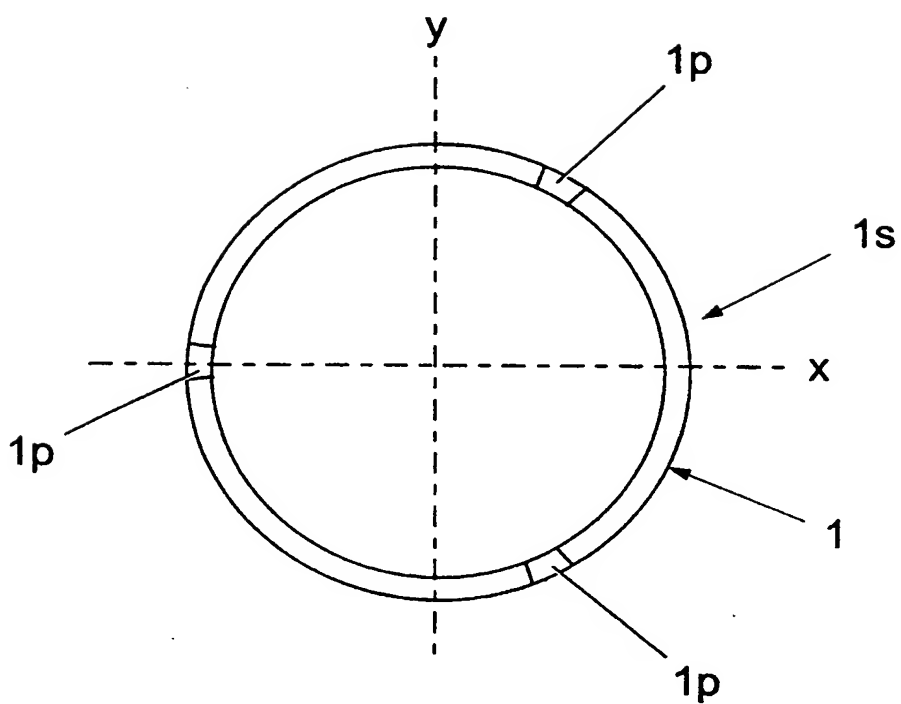
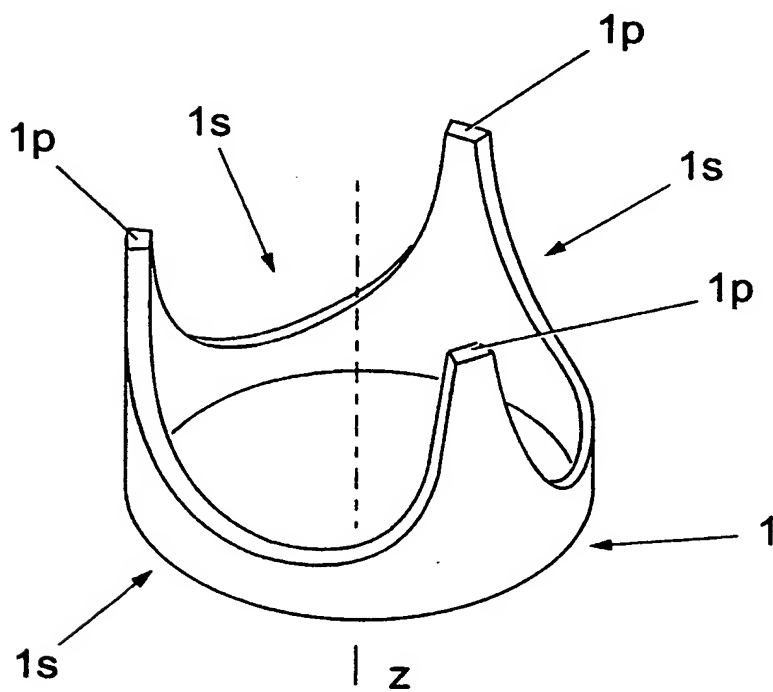


Fig. 5

6 / 8

*Fig. 6a**Fig. 6b*

7 / 8

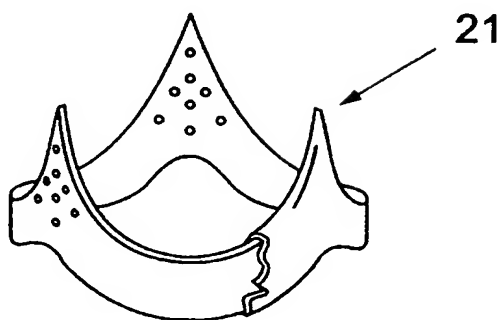
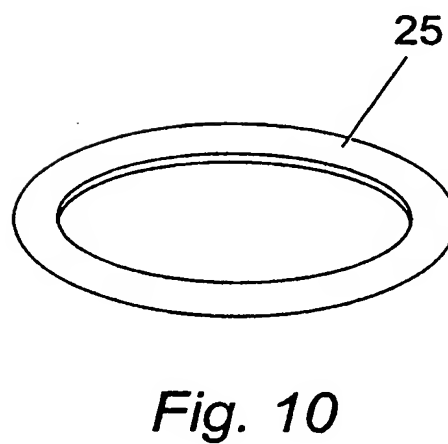
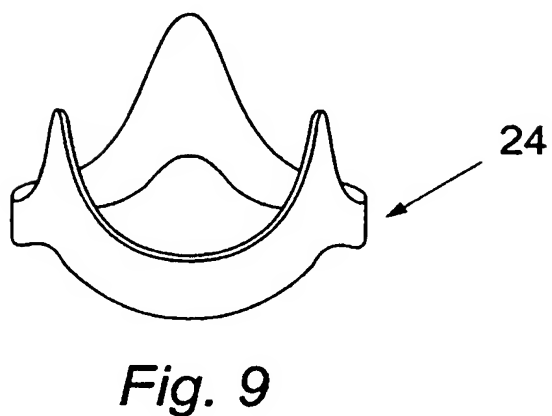
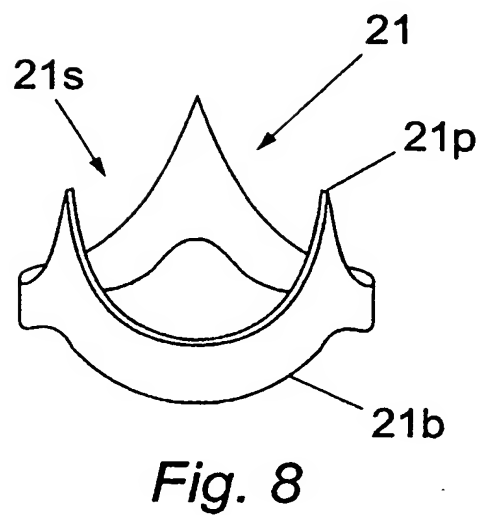
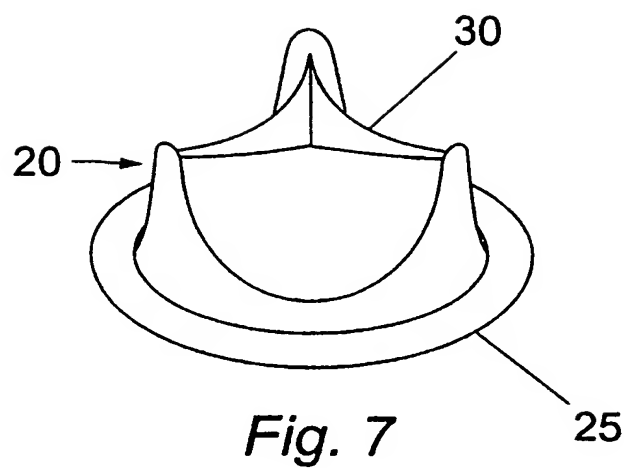


Fig. 11

8 / 8

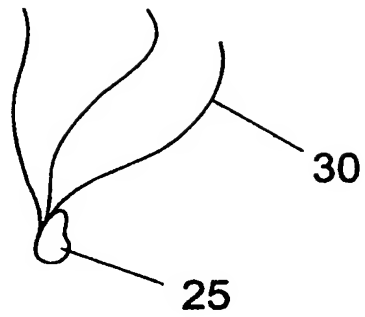


Fig. 12

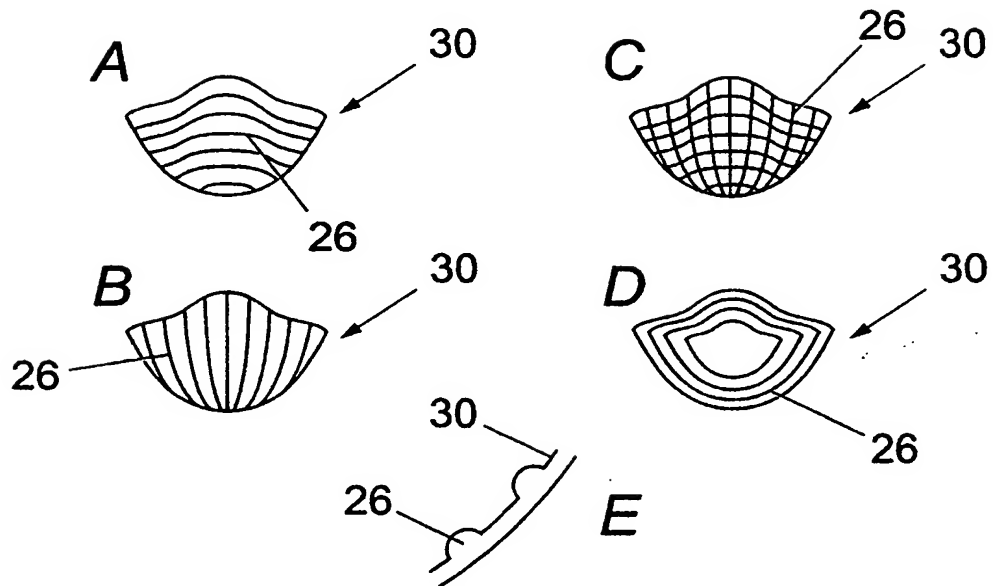


Fig. 13

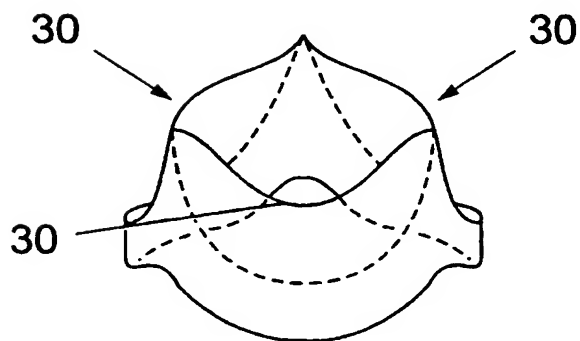


Fig. 14

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 98/00211

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 93 18721 A (UNIVERSITY OF LEEDS) 30 September 1993 see abstract	1
A, P	US 5 653 749 A (LOVE) 5 August 1997 see column 13, line 14 - column 14, line 14	1
A	EP 0 193 987 A (STICHTING VOOR DE TECHNISCHE WETENSCHAPPEN) 10 September 1986 see abstract	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

28 April 1998

Date of mailing of the international search report

12/05/1998

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern: al Application No

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9318721 A	30-09-1993	AT 161409 T	15-01-1998
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		EP 0632711 A	11-01-1995
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		JP 61247447 A	04-11-1986
		US 4731074 A	15-03-1988

1 Particularly preferred materials for use in fabrication
2 of prosthetic valves according to the present invention
3 are based on those disclosed in US Patent Nos 5,393,858
4 and 5,403,912, International Patent Application No
5 PCT/AU97/00619 and Australian provisional Patent
6 Application Nos P07002, P07616 and P07878.

7
8 An embodiment of the invention will now be described by
9 way of example with reference to the accompanying
10 drawings in which:

11
12 Fig. 1a and b show a valve in perspective view;
13 Fig. 2 shows a perspective view of a Fig. 1 valve
14 showing the spherical and conical portions;
15 Fig. 3 shows a sectional view through a leaflet of
16 the Fig. 1 and Fig. 2 valves;
17 Fig. 4 shows a side sectional view of the Fig. 1
18 valve;
19 Fig. 5 shows a perspective view of the valve when
20 open;
21 Fig. 6 shows a plan and a perspective view of the
22 frame;
23 Fig. 7 shows a perspective view of a second valve;
24 Fig. 8 shows a perspective view of the frame of
25 the Fig. 7 valve;
26 Fig. 9 shows a sleeve of the Fig. 7 valve in
27 perspective view;
28 Fig. 10 is a perspective view of a sewing ring of
29 the Fig. 7 valve;
30 Fig. 11 shows a perspective view of the Fig. 8
31 frame partially cut-away;
32 Fig. 12 shows a side sectional view of the
33 leaflets of the Fig. 7 valve;
34 Fig. 13 shows plan views (a, b, c and d) and a
35 cross section (e) of the leaflets indicating
36 possible ribbing configurations; and

Fig. 14 shows a perspective view of integrally moulded leaflets of the Fig. 7 valve.

Referring now to the drawings, a prosthesis according to the invention has a generally annular frame 1 with three posts 1P and three scallops 1S. The valve frame 1 is preferably formed from a rigid polymer such as polyetheretherketone or high modulus polyurethane, and is tri-symmetric with an axis of symmetry defined by the axis of blood flow through the valve. The external surface of the frame 1 is generally cylindrical with diameter D, and diverging to the tips of the posts P. For a given diameter D, the thickness of the valve frame 1 is typically 0.05 D.

The three scallops 1S and posts 1P are equally spaced at 120° intervals around the frame. A leaflet 10 is attached along the free edge of each scallop 1S and is supported by adjacent posts 1P. The three leaflets 10 are thus also spaced at 120° intervals around the frame 1.

Each leaflet 10 is identical, and has a truncated spherical surface 10S adjacent to its free edge. The spherical surface 10S is joined tangentially to a truncated conical surface 10C. The half angle of the truncated cone is 37.5°, but can be any angle in the range from 30° to 45° as shown in Fig. 3. The radius of the sphere is approximately $D/2 - 0.5(\text{mm})$, but can be between $D/2$ and $D/2 - 2(\text{mm})$. The leaflet surface is axi-symmetrical with the axis of symmetry being perpendicular to the axis of the valve frame and blood flow.

The free edge of each leaflet lies in a plane XY

1 perpendicular to the axis of intended blood flow
2 through the valve (Z). Fig. 3b shows the leaflet
3 geometry in the XY plane, and Fig. 4 shows the leaflet
4 geometry in the XZ plane.

5
6 The valve is disposed eg in vascular tissue with the
7 post 31 and free edges of the leaflets pointing
8 downstream. The leaflet geometry is designed to
9 encourage the opening of the valve leaflet from the
10 base of the valve. An increase in pressure upstream of
11 the valve causes the conical portions 10C at the base
12 of the leaflets to diverge first. The conical surface
13 can buckle to an open position very easily with minimal
14 resistance, and thus the valve can open under very low
15 upstream pressures. The divergence of the conical
16 sections 10C initiates divergence of the spherical
17 portions 10S.

18
19 The spherical portions 10S of the leaflets 10 are
20 easily opened following the divergence under upstream
21 pressure of the conical portions 10C, and under
22 increased downstream pressure, seal against one another
23 more effectively than a conical or a flat surface.

24
25 The sealing of the leaflets and competence of the
26 valves may be further enhanced by extending the
27 leaflets 1 to 2mm above the top of the valve posts,
28 varying the leaflet geometry above the post slightly to
29 bring the leaflets into direct opposition.

30
31 Figs. 7-13 show a second embodiment of a valve
32 according to the invention. The second valve 20 has
33 three leaflets 30 of flexible polyurethane located on a
34 support frame 21, a protective shield 24 for the
35 leaflets 30, and a sewing ring 25 for surgical
36 insertion.

1 The frame 21 has 3 posts 21P, each tapering to a point
2 from a base 21B. The posts and the base define 3
3 scallops 21S. The lower (upstream) edge of the base
4 21B is scalloped to conform generally to the scallops
5 21S receiving the leaflets 30.

6
7 A metal frame 21 is preferred and can provide maximum
8 strength and minimum frame thickness; the frame 21
9 could be dip coated with polymer. Apertures, grids or
10 a mesh surface could enhance metal/polymer adhesion.

11
12 The primary function of the frame 21 is to support the
13 base of the leaflets 30, giving a stable and
14 predictable geometry to the base of the leaflets 30.
15 The origin of the leaflets from the frame should be at
16 an optimised angle to minimise flexion stresses during
17 leaflet motion, and to spread the zone of transition
18 from full flexibility to full rigidity as widely as
19 possible. A seamless attachment of leaflet 30 to frame
20 21 is desirable to minimise the possibility of
21 separation of leaflet 30 from frame 21.

22
23 A degree of flexibility of the frame 21 will be
24 desirable to reduce stress on the leaflets, but
25 resistance to creep is important.

26
27 An outer sleeve 24 is provided to surround the posts
28 and frame, and to provide protection to the leaflets 30
29 from contact with adjacent tissues, particularly
30 ventricular myocardium in the case of the mitral valve,
31 and aortic wall in the case of the aortic valve. The
32 sleeve extends to beyond the edges of the posts.

33
34 The frame 21 also provides a secure anchorage for a
35 sewing ring 25 to allow surgical insertion.
36 Additionally, the frame can provide a temporary support

1 for a mounting system to allow surgical handling during
2 implantation of the valve.

3

4 Ideally, the frame 21 should be attached to the sewing
5 ring 25 in a manner which allows the implanted valve 20
6 to be rotated by the surgeon to optimise the position
7 of the frame posts.

8

9 Ideally, to minimise the risk of injury to the leaflets
10 30 during surgical implantation, and to facilitate
11 accurate and secure placement of the sewing ring 25,
12 the frame 21 should be separable from the sewing ring
13 25, and be readily and securely attachable at the time
14 of surgery following completion of sewing ring 25
15 insertion.

16

17 Overall height of the valve should be as low as is
18 compatible with good leaflet stability and reasonable
19 stress. The base of the leaflets 30 should be located
20 as close to the inflow aspect of the valve as possible,
21 and the sewing ring 25 should be mounted a distance
22 from the inflow aspect to reduce post protrusion as
23 much as possible.

24

25 The geometry of the leaflets 30 is preferably optimised
26 for even spread of stress during opening and closing,
27 and there should be substantial zones of leaflet 30
28 apposition. The leaflets 30 should preferably open at
29 low transvalvar pressure levels to allow satisfactory
30 use in small sizes in the mitral position, as well as
31 to gain optimal haemodynamic function. Hydrodynamic
32 performance in terms of pressure drop should rival that
33 of bileaflet mechanical valves rather than
34 bioprosthetic valves, and that of bioprosthetic valves
35 in terms of regurgitant flow.

36

1 Flexible three leaflet valves have essentially two
2 stable positions for the leaflets - open and closed.
3 The transition between the open and closed positions
4 involves a process of rapid buckling, which inflicts
5 rapid changes in shape on the leaflet accompanied by
6 abrupt angulation of the leaflet material and areas of
7 high stress concentration. It is possible to minimise
8 this source of transient, repetitive high stress by
9 careful leaflet geometric design.

10
11 The leaflet 30 can be formed with "memory" for the
12 optimised mid-buckling position allowing minimal
13 internal stress at the most vulnerable part of its
14 movement cycle. The leaflets 30 can be dip moulded in
15 a "mid-buckling" position. This offers a solution to
16 the problem of dip moulding three leaflets 30 within a
17 complete frame 21. However, it also helps to ensure
18 that the buckling process is predictable and
19 controlled, with minimisation and distribution of
20 stress during buckling. To ensure that the valve
21 assumes a closed position when unloaded a second dip
22 could be applied while the valve was in the closed
23 position. The same effect may be achievable by heat
24 annealing in the closed position. Whichever method is
25 used, only sufficient memory should be induced in the
26 leaflet to allow closure, but not so much as to require
27 the level of opening transvalve pressure gradient that
28 would be present if the leaflet were moulded in the
29 closed position. It may also be helpful to carry out a
30 third dip mould in the open position (or further heat
31 annealing) to impose a uniform, uncrimped geometry on
32 the open valve. The thickness of additional dip coats
33 would be controlled by adjusting the concentration of
34 the dipping solution.

35
36 A further option for both strengthening the leaflets 30

1 and controlling buckling is provided by incorporating
2 reinforcing ribs 26 in the polyurethane leaflets 30.
3 This has the effect of making the leaflet 30 stiffer in
4 one direction (the direction of the ribs 26) than in
5 the perpendicular direction. The anisotropic
6 properties of the native aortic valve (and porcine
7 bioprosthetic valves) could be mimicked through
8 circumferential ribbing on a polyurethane leaflet. The
9 concept can be extended to the use of grid-like ribs 26
10 or even concentrically placed circular or oval ribs 26
11 which would influence leaflet buckling in a predictable
12 fashion. Such ribs 26 can be formed in a dip moulded
13 valve, for example, by carefully etching the leaflet 30
14 dipping formers. In order to avoid potential flow
15 disturbance, it would be desirable to form the ribs 26
16 on the leaflet outflow rather than on the inflow
17 surface.

18
19 The leaflet 30 may be dip-moulded separately, to
20 facilitate an adequate surface area for the leaflets
21 30, as well as the ribbing pattern of polyurethane as
22 an inherent part of the leaflet 30 (protruding from the
23 outflow aspect of the leaflets), and may be assembled
24 onto a frame 21 using locating pins and holes.
25 Alternatively, it is possible to dip mould all three
26 leaflets as a complete unit which could be bonded or
27 fixed onto a frame eg with the aid of locating pins and
28 corresponding holes in the frame. The sleeve 24 can
29 include a clamp and could extend beyond the posts to
30 assist in shielding the leaflets from myocardial or
31 aortic wall impingement.

32

33 Example 1

34

35 A valve was manufactured as shown in Figure 2. The
36 base has an approximate outer diameter of 23.8mm with an

1 inner diameter of 22.4mm.

2

3 The posts extend approximately 17mm from the base of
4 the frame and in this embodiment the width of the top
5 of each post is 1.4mm with a thickness of 0.7mm

6

7 The valve frame is manufactured from
8 polyetheretherketone and coated with ELASTEON CSIRO at
9 a thickness of 0.2mm.

10

11 To fabricate the coated valve frame is placed over a
12 solid mould and leaflets are formed by dip moulding
13 thereby integrating them to the frame. The leaflet
14 material is ELASTEON CSIRO polyurethane with a
15 thickness of between 100 to 200 μm .

16

17 Alternative examples of a prosthetic valve according to
18 the present invention involve using a high modulus
19 polyurethane frame ($E > 500 \text{ MPa}$) or using CHRONOFLEX or
20 TECOTHANE polyurethanes with an elastic modulus in the
21 range 5-15 MPa.

22

23 Modifications and improvements can be incorporated
24 without departing from the scope of the invention. For
25 instance, the frame can be made of a biocompatible
26 polymer, metal, or composite. The frame can be coated
27 with polyurethane to allow integration of the leaflets,
28 and can be flexible so as to allow the post to deflect
29 (eg by approximately 0.05D) on closure of the valve
30 under pressure.

31

1 **CLAIMS**

- 2
- 3 1. A cardiac valve prosthesis comprising a frame and
4 two or more leaflets attached to the frame,
5 wherein at least one of the leaflets comprises a
6 first portion which has a generally spherical
7 surface, and a second portion which has a
8 generally conical surface.
- 9
- 10 2. A prosthesis as claimed in claim 1 wherein the
11 surfaces of the first and second portions are
12 respectively partially spherical or conical.
- 13
- 14 3. A prosthesis as claimed in claim 1 or claim 2
15 wherein the frame has a generally circular cross
16 section with two or more posts (in an equal number
17 to the number of leaflets) extending in the same
18 direction from a base such that the mouth of the
19 valve formed by the base is held open.
- 20
- 21 4. A prosthesis as claimed in any of the preceding
22 claims wherein the leaflets are attached to the
23 frame between the posts and each have a free edge
24 adjacent to the ends of the posts which can seal
25 together at the ends of the posts.
- 26
- 27 5. A prosthesis as claimed in any of the preceding
28 claims wherein the conical portion is located
29 adjacent to the base of the prosthesis, and the
30 spherical portion is located adjacent to the free
31 edge.
- 32
- 33 6. A prosthesis as claimed in any of the preceding
34 claims wherein the leaflets are identical.
- 35
- 36 7. A prosthesis as claimed in any of the preceding

- 1 claims wherein the prosthesis comprises three
2 leaflets and three posts.
3
- 4 8. A prosthesis as claimed in any of the preceding
5 claims wherein the leaflets are flexible.
6
- 7 9. A prosthesis as claimed in any of the preceding
8 claims wherein the leaflets have a defined
9 boundary between the first (spherical) portion and
10 the second (conical) portion.
11
- 12 10. A prosthesis as claimed in any of claims 1 to 8
13 wherein the boundary between the first and second
14 portions is phased by adopting a sphere of
15 gradually increasing radius merging with the
16 conical portion and the free edge of the leaflets
17 (or a portion thereof) has a generally spherical
18 surface.
19
- 20 11. A prosthesis as claimed in any of the preceding
21 claims wherein the leaflets comprise a biostable
22 material, such as biostable polyurethane CSIRO,
23 and are dip moulded thereby integrating the
24 leaflets to the supporting frame and posts.
25
- 26 12. A prosthesis as claimed in any of the preceding
27 claims wherein the leaflets are approximately 100-
28 200 μm .
29
- 30 13. A prosthesis as claimed in any of the preceding
31 claims wherein the leaflets vary in thickness, so
32 as to incorporate thick-walled areas and adjacent
33 thin-walled areas.
34
- 35 14. A prosthesis as claimed in any of the preceding
36 claims wherein the leaflet surface is axi-

1 symmetrical, with the axis of symmetry being
2 perpendicular to the axis of the valve frame and
3 the intended direction of blood flow.

15. A prosthesis as claimed in any of the preceding
claims wherein the diameter of the frame is
distance D and the radius of the sphere lies
between $D/2$ and $D/2-2(\text{mm})$.

10 16. A prosthesis as claimed in any of the preceding
11 claims wherein the conical portion is truncated
12 and has a half angle within the range 30° to 45° .

14 17. A prosthesis as claimed in any of the preceding
15 claims wherein the pressure required to open the
16 valve is defined by the equation $\frac{E t^3}{R}$ where E is
17 the elastic modulus, t is the leaflet thickness
18 and R is the radius of curvature.

21 18. A prosthesis as claimed in any of the preceding
22 claims wherein the prosthesis incorporates an
23 escape path for trapped air.

25 19. A prosthesis as claimed in any of the preceding
26 claims wherein the prosthesis further comprises
27 means for protecting the prosthesis from post
28 ensnarement with an implanting suture.

1 / 8

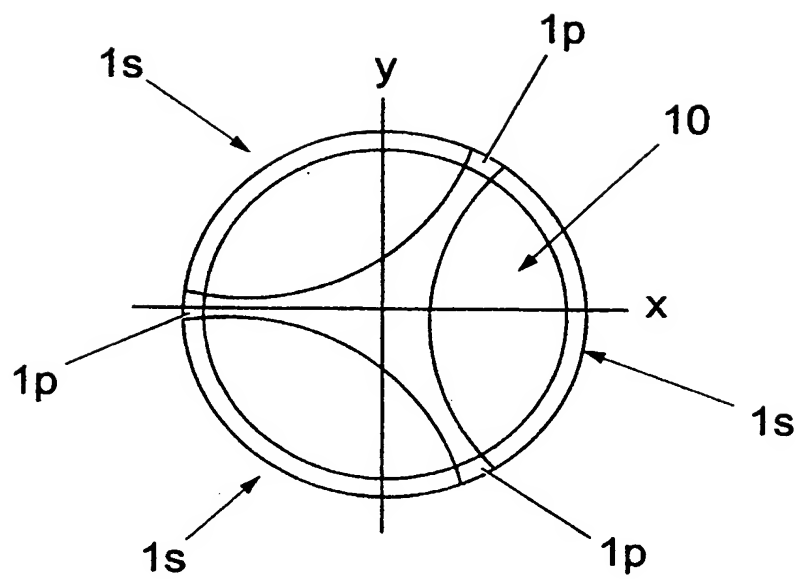


Fig. 1a

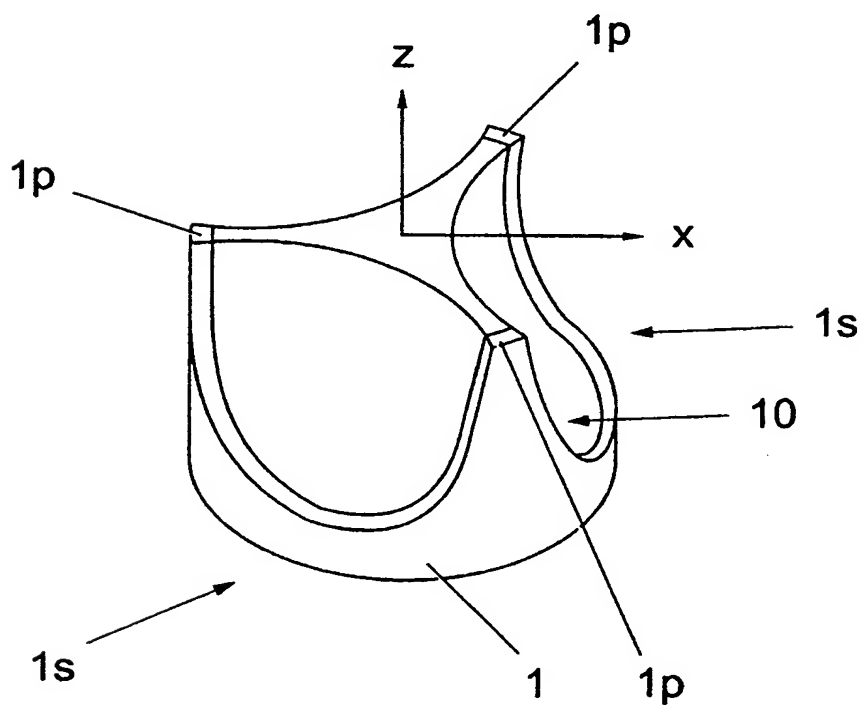


Fig. 1b

2 / 8

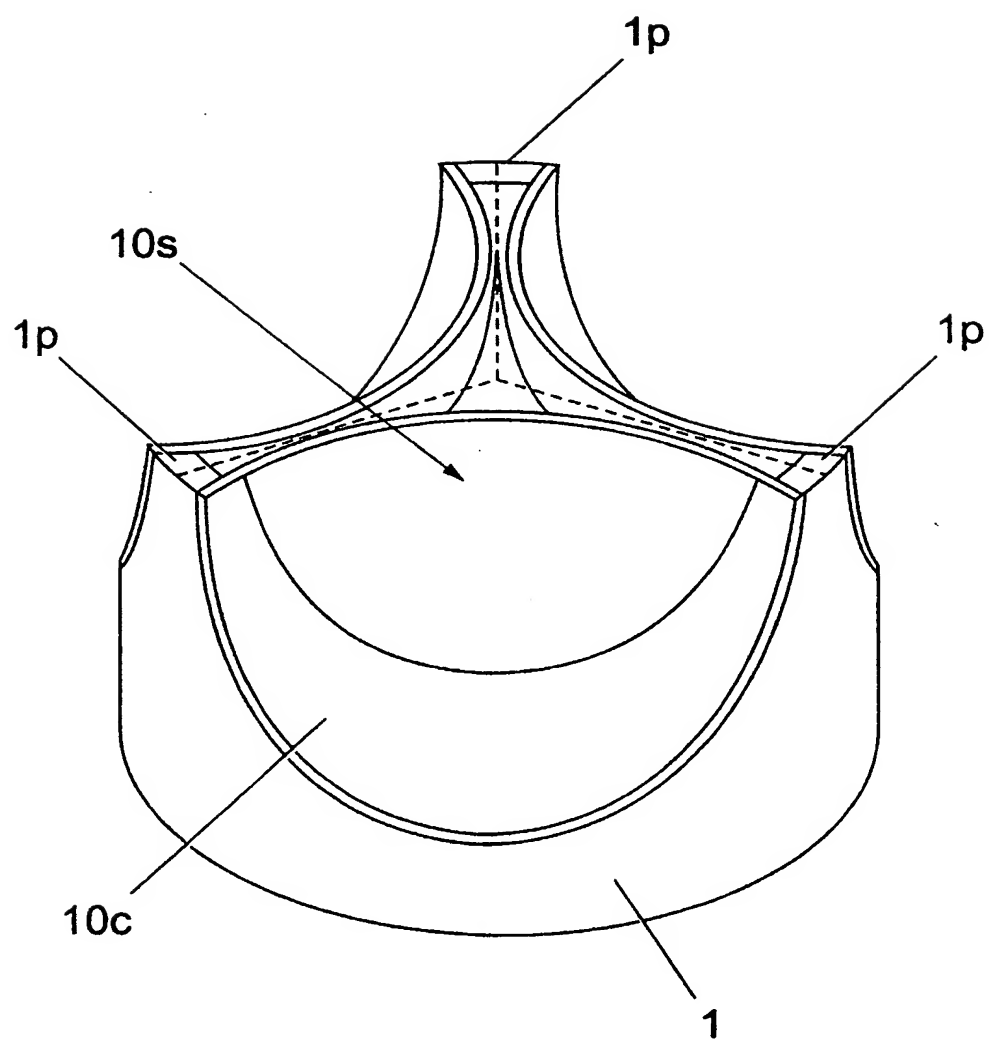
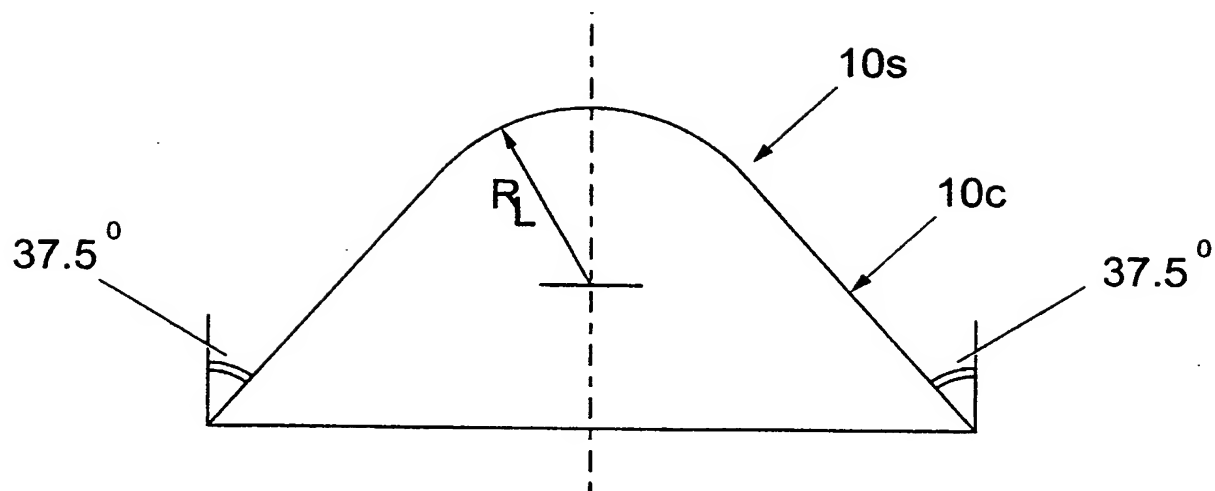
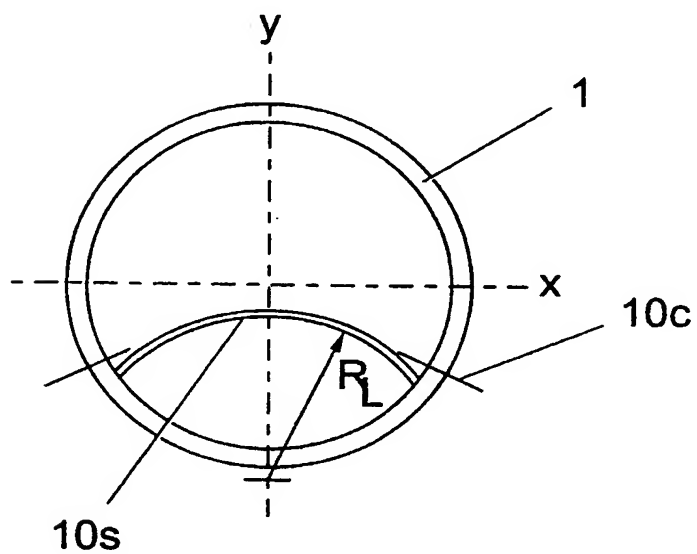


Fig. 2

3 / 8

*Fig. 3a**Fig. 3b*